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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,162	05/31/2001	Isaiah J. Fidler	UTSC:643US/SLH	8776

7590 11/19/2002

FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/19/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/872,162

Applicant(s)

FIDLER ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-194 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-194 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Claims 1-194 are pending in the present application.

Election/Restrictions

Group Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-78, 105-117 and 174-177, drawn to methods of invoking an immune response in an organism, of treating a mammal having a tumor, of treating metastatic tumor cells in an organism, of treating a mammal having a disease state and of recruiting immune cells to a specific site in a host comprising the administration of an insect cell composition; and a kit comprising an insect composition, classified in class 424, subclasses 93.1, 93.2.
- II. Claims 79-104, 159-169 and 178-194, drawn to a vaccine composition comprising an antigenic compound, an insect composition and a pharmaceutically acceptable carrier; and methods of establishing immunological memory or inducing an antitumor immune response comprising providing a host organism a pharmaceutical composition comprising an antigenic compound or a tumor antigen and an insect cell composition; and a method of preparing the same vaccine composition, classified in class 424, subclasses 93.1, 93.2.

- III. Claims 118-132 and 170-173, drawn to a method of stimulating immune cells comprising contacting the immune cells with an insect cell composition and a method of inducing an immune response comprising isolating immune cells from a host, contacting said cultured cells with an insect cell composition, and reintroducing said immune cells into said host, classified in class 424, subclasses 93.1, 93.2.
- IV. Claims 133-144, drawn to a method of treating cancer comprising isolating cancer cells from a host, rendering said cancer cells inactive, and reintroducing said inactivated cancer cells into said host in a pharmaceutical composition further comprising an insect composition, classified in class 424, subclasses 93.1, 93.2.
- V. Claims 145-158, drawn to a method of treating cancer comprising isolating cancer cells from a host, rendering said cancer cells inactive, isolating immune cells from said host, contacting said immune cells with a composition comprising said inactive cancer cells and an insect cell composition, and administering to said host a pharmaceutical composition comprising said immune cells, classified in class 424, subclasses 93.1, 93.2.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I to V differ one from the other of the starting materials, different method steps and different desired end-results that require different technical considerations. For examples, the method of Group I does not require the co-

administration of an antigenic compound as required by the method of Group II, nor does it need the isolation of immune cells or contact of an insect cell composition with the immune cells as required by the method of Group III, nor does it have the same steps recited in the methods of Group IV and V. Similarly, the method of Group II does not the isolation of any immune cells or contacting the immune cells with an insect cell composition as required by the method of Group II, nor does it have the same steps recited by the methods of Group IV and V. The same arguments can be made for the distinct methods of Groups III, IV and V.

Because these inventions are distinct for the reasons set forth above, it would be unduly burdensome for the examiner to search and/or consider the patentability of all of the inventions in a single patent application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect the invention of Group I, it contains claims directed to the following patentably distinct species:

Claims 1-2, 34-35, 47-48, 60-61, 73-74, 105-106 and 174-175 are generic to a plurality of disclosed patentably distinct species of an immunomodulator comprising: (a) IFN β ; (b) IL-2; (c) IL-7; (d) IL-15; (e) IL-16; and (f) GM-CSF.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Group I also contains claims directed to the following patentably distinct species:

Claims 1, 11-13, 34, 38-40, 47, 51-53, 60, 64-66, 73-74, 105, 109-111 are generic to a plurality of disclosed patentably distinct species of an exogenous construct comprising: (a) a construct encoding an immunomodulator or a cytokine; (b) a construct encoding a tumor antigen; and (c) a construct encoding a foreign antigen.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect a construct encoding a tumor antigen in species (b), claims 1, 11-13, 16-17, 34, 38-40, 43-44, 47, 51-53, 56-57, 60, 64-66, 69-70, 73-74, 105, 109-111 and 114-115 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named tumor antigen as listed in the Markush group of claim 17 or 44 or 57 or 70 or 115.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, Group I also contains claims directed to the following patentably distinct species:

Claim 1 is generic to a plurality of disclosed patentably distinct species of an insect cell composition comprising: (a) intact insect cell composition; (b) disrupted insect cell composition; (c) lyophilized insect cell composition; and (d) freeze/thawed insect cell composition.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group II, it contains claims directed to the following patentably distinct species:

Claims 79-80, 92-93, 159-160, 178-179 are generic to a plurality of disclosed patentably distinct species of an immunomodulator comprising: (a) IFN β ; (b) IL-2; (c) IL-7; (d) IL-15; (e) IL-16; and (f) GM-CSF.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Group II also contains claims directed to the following patentably distinct species:

Claims 79, 83-85, 92, 96-98, 159, 163-165, 178, 183-185 are generic to a plurality of disclosed patentably distinct species of an exogenous construct comprising: (a) a construct encoding an immunomodulator or a cytokine; (b) a construct encoding a tumor antigen; and (c) a construct encoding a foreign antigen.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect a construct encoding a tumor antigen in species (b), claims 79, 83-85, 88-89, 92, 96-98, 101-102, 159, 163-165, 168-169, 178, 183-185 and 188-189 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named tumor antigen as listed in the Markush group of claim 89 or 102 or 169 or 189.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group III, it contains claims directed to the following patentably distinct species:

Claims 118-119 and 170-171 are generic to a plurality of disclosed patentably distinct species of an immunomodulator comprising: (a) IFN β ; (b) IL-2; (c) IL-7; (d) IL-15; (e) IL-16; and (f) GM-CSF.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Group III also contains claims directed to the following patentably distinct species:

Claims 118 and 124-126 are generic to a plurality of disclosed patentably distinct species of an exogenous construct comprising: (a) a construct encoding an immunomodulator; (b) a construct encoding a tumor antigen; and (c) a construct encoding a foreign antigen.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect a construct encoding a tumor antigen in species (b), claims 118, 124-126, 129-130 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named tumor antigen as listed in the Markush group of claim 130.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group IV, it contains claims directed to the following patentably distinct species:

Claims 133 and 134 are generic to a plurality of disclosed patentably distinct species of an immunomodulator comprising: (a) IFN β ; (b) IL-2; (c) IL-7; (d) IL-15; (e) IL-16; and (f) GM-CSF.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Group IV also contains claims directed to the following patentably distinct species:

Claims 133 and 139-140 are generic to a plurality of disclosed patentably distinct species of an exogenous construct comprising: (a) a construct encoding an immunomodulator; and (b) a construct encoding a tumor antigen.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect a construct encoding a tumor antigen in species (b), claims 133, 139-140 and 143-144 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named tumor antigen as listed in the Markush group of claim 144.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group V, it contains claims directed to the following patentably distinct species:

Claims 145 and 146 are generic to a plurality of disclosed patentably distinct species of an immunomodulator comprising: (a) IFN β ; (b) IL-2; (c) IL-7; (d) IL-15; (e) IL-16; and (f) GM-CSF.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Group V also contains claims directed to the following patentably distinct species:

Claims 145 and 152-154 are generic to a plurality of disclosed patentably distinct species of an exogenous construct comprising: (a) a construct encoding an immunomodulator; and (b) a construct encoding a tumor antigen.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect a construct encoding a tumor antigen in species (b), claims 145, 152-154 and 157-159 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named tumor antigen as listed in the Markush group of claim 159.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

Art Unit: 1636

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Additionally, please correct for the appropriate dependency of claims 74-76, 80-82 and 124 because as written it is unclear what exactly Applicants claim.

Art Unit: 1636


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.


DAVE T. NGUYEN
PRIMARY EXAMINER